IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

PAR PHARMACEUTICAL, INC., PAR STERILE PRODUCTS, LLC, and ENDO PAR INNOVATION COMPANY, LLC, Plaintiffs, v. AMNEAL EU, LTD., *et al.*, Defendants.	C.A. No. 3:20-cv-18322 (BRM-DEA) **CONFIDENTIAL – ELECTRONICALLY FILED UNDER SEAL**

MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS PLAINTIFFS' AMENDED COMPLAINT

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INTRODUCTION

This is a Hatch-Waxman Act patent infringement action in which Plaintiffs ("Par") allege that Defendants ("Amneal") have infringed Par's patents by filing two abbreviated new drug applications seeking FDA approval to market and sell generic versions of Par's VASOSTRICT® product for the treatment of septic and post-cardiotomy shock. Par alleges that upon approval, Amneal will market and sell its generic products in a manner that will induce doctors, nurses, and other medical professionals to administer vasopressin in a manner that infringes Par's patents. Par asserts claims for infringement of the two patents in suit under 35 U.S.C. § 271(e)(2) (Counts I, III, V, and VII), and for declaratory judgments that if Amneal's ANDAs are approved, Amneal will induce others to infringe those patents and hence be liable for infringement under 35 U.S.C. § 271(b) (Counts II, IV, VI, and VIII).

In its motion to dismiss Par's Amended Complaint, Amneal first argues that Par's § 271(e)(2) claims fail because Amneal does not seek FDA approval for the use of vasopressin claimed in Par's patents. Amneal is wrong. [redacted]

Amneal's remaining arguments are all one form or another if its assertion

that Par's claims are too speculative, either to state a claim for infringement or to sustain subject matter jurisdiction over the declaratory judgment claims. However, Amneal mischaracterizes Par's allegations, falsely asserting that Par's claims depend on the FDA's future approval of amendments to Par's NDA and Amneal's ANDAs. They do not. Par alleges in detail how and why, even absent any change in the proposed label for VASOSTRICT® or Amneal's proposed vasopressin products, Amneal will market and sell its products with the knowledge and specific intent that it will be used to treat patients in accordance with Par's patented treatment regimens, and thereby induce infringement of Par's patents. Amneal has not submitted any declaration or other evidence to dispute the veracity of those allegations, and for purposes of Amneal's motion to dismiss, the Court must accept them as true.

Accordingly, the Court should deny Amneal's motion in its entirety.

FACTUAL BACKGROUND[1]

A. VASOSTRICT® and the Patents in Suit

Par makes and sells VASOSTRICT®, a vasopressin formulation commonly used to treat septic shock and post-cardiotomy shock in hospital rooms and ICUs

[1] This Factual Background is based on the allegations set forth in Par's First Amended Complaint (D.I. 14) ("Am. Compl."). Amneal has not submitted any declarations or other evidence with its moving papers disputing any of the facts set forth herein.

around the country. Am. Compl. at ¶¶ 24, 30.[2] These are serious, life-threatening conditions involving significant drops in blood pressure, and VASOSTRICT® serves to increase patients' blood pressure even when the provision of fluids and catecholamines fails. *Id*. at ¶¶ 24, 28-30.

Over the years, Par has invested substantial resources in the research and development of safer and more effective formulations and uses of vasopressin. *Id*. at ¶ 24. Most recently, Par discovered that patients with two particular genotypes—i.e., those with what is known as an LNPEP AA or AT rs4869317 genotype ("AA or AT genotyped patients")—unexpectedly exhibit lower concentrations of vasopressin in the bloodstream and increased vasopressin clearance than those with other genotypes. *Id*. at ¶¶ 35-37.[3] Further research demonstrated that treating AA or AT genotyped patients suffering from septic shock and post-cardiotomy shock differently than other patients would result in improved survival rates and reduced adverse events. *Id*. at ¶ 37. In particular, Par

[2] Vasopressin is a polypeptide hormone that causes contraction of vascular and smooth muscle cells. *Id*. at ¶ 23.

[3] A "genotype" is an individual's collection of genes. *Id*. at ¶ 34. Genes consist of DNA, which is a molecule composed of strands of four types of nucleotides: A, T, C and G. *Id*. at ¶ 33. Each of the nucleotides on one side of the strand pairs with a specific nucleotide on the other side of the strand, and this makes up the double helix, and accordingly, the genetic code for each gene is written in the form of a string of As, Ts, Cs, Gs. *Id*. Human beings typically carry two copies of each gene, and the "LNPEP AA and AT rs4869317" for the above-recited genotypes refer to the nucleotides at a particular location. *See id*. at ¶¶ 33-35.

discovered that patents with AA or AT genotypes could and, if medically warranted under the circumstances, should be treated with a dose of vasopressin that is higher than the currently-labelled maximum dose of VASOSTRICT®. *Id.* These new treatment regimens will improve patient outcomes as medical practitioners begin to fold these teachings into their use of vasopressin to treat patients with septic or post-cardiotomy shock. *Id*. at ¶ 41.

Par has received two patents on these new, innovative treatment regimens: the '435 Patent and the '278 Patent. *Id*. at ¶¶ 39-40. Par has filed a request with the FDA seeking approval for an amendment to the label for VASOSTRICT® to include this important new information on improved methods of administering VASOSTRICT® to patients with certain specified genotypes. *Id*. at ¶ 42. Par has also submitted information regarding the Patents in Suit to the FDA for listing in the Orange Book with respect to VASOSTRICT®. *Id*. at ¶ 43.

The '435 Patent claims "method[s] of increasing blood pressure to a target blood pressure in a human patient with septic shock wherein the patient has an LNPEP AA or AT rs4869317 genotype." *See* Am. Compl., Ex. A at claim 1. The '278 Patent claims similar methods, except for treating patients with a different type of vasodilatory shock—*i.e.*, post-cardiotomy shock rather than septic shock. *See id.*, Ex. B at claim 1.

B. Amneal's Proposed Vasopressin Product

In 2019, Amneal submitted two Abbreviated New Drug Applications ("ANDAs") seeking FDA approval to market generic vasopressin products, referencing Par's VASOSTRICT® products as the reference listed drug (Amneal's "Proposed Vasopressin Products"). *Id*. at ¶¶ 44-45. Amneal is seeking FDA approval to market its Proposed Vasopressin Products prior to expiration of the Patents in Suit. *Id*. at ¶ 46. [redacted]

Upon FDA approval, Amneal will market and sell its Proposed Vasopressin Products as generic substitutes for VASOSTRICT®, to be used and administered in the same manner as VASOSTRICT®. *Id*. at ¶ 49. And, because Amneal's Proposed Vasopressin Products would not be "AB"-rated to VASOSTRICT®, Amneal cannot rely on its generic products being automatically substituted for VASOSTRICT® by pharmacists. *Id*. at ¶ 50. Accordingly, Amneal will instead have to use its sales force to affirmatively market its ANDA Products to hospitals

and group purchasing organizations ("GPOs") and try to convince them to switch from VASOSTRICT® to its Vasopressin Product. *Id.* In doing so, Amneal's sales force will make affirmative representations to its customers that Amneal's Vasopressin Products are equivalent to VASOSTRICT® and can and should be administered in the same manner as VASOSTRICT®. *Id.*

Amneal will do so with the knowledge and expectation that physicians will treat patients based on the most up-to-date clinical information available—including that AA and AT genotyped patients can and should be treated in accordance with the new treatment regimens claimed in the Patents in Suit. *Id*. at ¶ 52. Indeed, it would be irresponsible for Amneal to do otherwise. *Id*. at ¶ 53. Vasodilatory shock, including septic shock and post-cardiotomy shock, is a life-threatening condition that needs to be treated on an emergent basis, and the proper treatment of patients suffering from vasodilatory shock can, quite literally, be a matter of life or death. *Id*. Failure to treat AA and AT genotyped patients with septic or post-cardiotomy shock using Par's new treatment regimens could lead to an adverse treatment outcome including, in a worst-case scenario, death. *Id*. Accordingly, Par expects that Amneal will act in accordance with the best interests of patients, and that, in doing so, Amneal will market and sell its Proposed Vasopressin Products (if approved) with explicit or implicit instructions, and the

specific intent, that its products be used to treat AA and AT genotyped patients with septic or post-cardiotomy shock as claimed in Par's patents. *Id*. at ¶ 54.

C. Amneal's Motion to Dismiss

Par commenced this suit in December 2020, alleging that Amneal's submission of its ANDAs to the FDA constitutes infringement of the '435 Patent under 35 U.S.C. § 271(e)(2) and seeking a declaratory judgment that Amneal's commercial manufacture, use, offer for sale, sale, and/or importation into the United States of its Proposed Vasopressin Products would induce infringement of the '435 Patent by others. D.I. 1. Par amended its complaint to add similar claims for the '278 Patent in March 2021. D.I. 14.

Amneal moves to dismiss Par's claims on both Rule 12(b)(6) and 12(b)(1) grounds: (a) Amneal argues that Par fails to state any valid claim, and hence moves to dismiss all eight Counts of the Amended Complaint under Rule 12(b)(6); and (b) Amneal argues that this Court lacks subject matter jurisdiction over Par's declaratory judgment claims (Counts II, IV, VI, and VIII), and hence moves to dismiss those claims under Rule 12(b)(1).[4]

[4] Par filed a similar suit in this District against Eagle Pharmaceuticals alleging infringement of the Patents in Suit based on Eagle's submission of an ANDA seeking FDA approval to market a generic vasopressin product prior to expiration of those Patents. C.A. No. 3:20-cv-18319 (BRM-DEA). Eagle also filed a motion to dismiss in that case, and as Amneal notes, Amneal's arguments mirror those of Eagle. *See* Amneal Br. at 1 n.1.

Amneal did not submit any declaration or other evidence disputing any of the facts alleged in the Amended Complaint. Amneal submitted copies of the current proposed labels for its Proposed Vasopressin Products as exhibits with its motion (*see* Exs. 1, 2 to the Declaration of Rebekah Conroy (D.I. 19-1)), but nothing more.

ARGUMENT

I. GOVERNING LEGAL STANDARDS

"To survive a motion to dismiss [for failure to state a claim], a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). "When there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief." *Id.* at 679. *See also Connelly v. Lane Const. Corp.*, 809 F.3d 780, 790 (3d Cir. 2016) (noting that the court must "assume all remaining factual allegations to be true, construe those truths in the light most favorable to the plaintiff, and then draw all reasonable inferences from them").

Federal courts have jurisdiction over declaratory judgment claims if "the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient

immediacy and reality to warrant the issuance of a declaratory judgment." *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007) (quoting *Maryland Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273 (1941)).[5] "A litigant need not await actual harm to seek a declaratory judgment, provided the probability of future harm is real and substantial." *Zinn v. Seruga*, No. 05-cv-3572 (WGB), 2006 WL 2135811, at *4 (D.N.J. July 28, 2006) (citing *Travelers Ins. Co. v. Obusek*, 72 F.3d 1148, 1150 (3d Cir. 1995). Indeed, "a party need not have engaged in the actual manufacture or sale of a potentially infringing product…"; instead "there must be a showing of 'meaningful preparation' for making or using that product." *Cat Tech LLC v. TubeMaster, Inc.*, 528 F.3d 871, 881 (Fed. Cir. 2008). "[A]n examination of the totality of the circumstances must be made to determine whether there is a controversy in a patent declaratory judgment action." *Danisco U.S. Inc. v. Novozymes A/S*, 744 F.3d 1325, 1330-31 (Fed. Cir. 2014) (citation omitted).

A Rule 12(b)(1) motion challenging subject matter jurisdiction may present either a facial challenge or a factual challenge to the Court's jurisdiction. *See Constitution Party of Pa. v. Aichele*, 757 F.3d 347, 357 (3d Cir. 2014). A facial

[5] The Declaratory Judgment Act provides that: "In a case of actual controversy within its jurisdiction ... any court in the United States ... may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought." 28 U.S.C. § 2201(a).

attack "considers a claim on its face and asserts that it is insufficient to invoke the subject matter jurisdiction of the court…" *Id*. at 358. "In reviewing a facial attack, the court must only consider the allegations of the complaint and documents referenced therein and attached thereto, in the light most favorable to the [claimant]." *Gould Elecs. Inc. v. U.S.*, 220 F.3d 169, 176-77 (3d Cir. 2000). On the other hand, a factual attack argues "there is no subject matter jurisdiction because the facts of the case—and here the District Court may look beyond the pleadings to ascertain the facts—do not support the asserted jurisdiction." *Constitution Party of Pa.*, 757 F.3d at 358. "Phrased differently, '[i]f a defendant does not challenge the facts alleged in the plaintiff's pleadings, a court may rule on the [12(b)(1)] motion by accepting these allegations as true.'" *New Jersey ex rel. McDonald v. Copperthwaite*, No. 3:13-cv-05559 (FLW) (LHG), 2014 WL 2208159, at *4 (D.N.J. May 28, 2014) (quoting *McCann v. Newman Irrevocable Trust*, 458 F.3d 281, 290 (3d Cir. 2006)).

Here, Amneal submitted no sworn testimony or other evidence disputing any of the facts alleged in the Amended Complaint. Instead, Amneal's motion "focus[es] on the allegations in [the Amended Complaint] and why those allegations assertedly do not give rise to subject matter jurisdiction." *In re Mobile Telecomms. Techs., LLC*, 247 F. Supp. 3d 456, 459 (D. Del. 2017). Accordingly, it is a facial attack, and in assessing Amneal's arguments, the Court "must accept as

true all material allegations set forth in the [Amended Complaint], and must construe those facts in favor of [Par]." *Constitution Party of Pa.*, 757 F.3d at 357 n.12 (quoting *Storino v. Borough of Point Pleasant Beach*, 322 F.3d 293, 296 (3d Cir. 2003)); *see also id*. at 358 (noting that "The Commonwealth filed the attack before it filed any answer to the Complaint or otherwise presented competing facts. Its motion was therefore, by definition, a facial attack").

II. AMNEAL'S RULE 12(B)(6) MOTION IMPROPERLY RELIES ON EVIDENCE OUTSIDE THE PLEADINGS

As a preliminary matter, Amneal's arguments under Rule 12(b)(6) that Par has failed to state any valid claim are procedurally improper because they are based on evidence outside the pleadings—i.e., the confidential proposed labels for its Proposed Vasopressin Products submitted as Exhibits 1 and 2 to its motion. *See* D.I. 19-1. "The general rule, of course, is that a district court ruling on a motion to dismiss may not consider matters extraneous to the pleadings." *West Penn Allegheny Health Sys., Inc. v. UPMC*, 627 F.3d 85, 97 n.6 (3d Cir. 2010) (quoting *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997)).

Amneal's attempt to justify its reliance on the label, based on Par's reference to Amneal's ANDAs in the Amended Complaint, is contrary to law. See Amneal Br. at 4 n.2. "[G]eneral references to an ANDA fall short of explicit reliance, precluding consideration of the ANDA in a ruling on a motion to dismiss." *Par Pharma., Inc. v. Hospira, Inc.*, No. 17-cv-944-JFB-SRF, 2018 WL 3343238, at *2

(D. Del. May 11, 2018) (refusing to consider portions of ANDA in conjunction with motion to dismiss where "references to Hospira's ANDA in the complaint…are limited to the fact of the ANDA's filing and to summarize its contents…"); *see also Cima Labs, Inc. v. Actavis Grp. HF*, No. 07-cv-893 (DRD), 2007 WL 1672229, at *4 (D.N.J. June 7, 2007) ("[A]lthough Plaintiffs refer to the ANDA in the Complaint, the reference is merely to the fact that the ANDA was filed and to describe generally the contents of the ANDA that was gleaned from the Paragraph IV Notice Letter. Thus, because Plaintiffs did not explicitly rely on the ANDA document, the ANDA will not be considered on this motion").

The Amended Complaint only makes general reference to Amneal's ANDAs and how Amneal will market its Proposed Vasopressin Products upon approval. And, although Par includes allegations about amendments it believes Amneal will have to make to the proposed labeling for that Products, Par does not cite to or rely on the contents of the current proposed labeling. Indeed, Par has not taken any discovery and does not know whether the exhibits attached are, in fact, the current proposed labeling and/or whether Amneal has submitted any proposed amendments or other changes to the labeling. Accordingly, Amneal's reliance on the proposed label is inappropriate, and the Court should disregard it and any arguments that rely on it. Because all of Amneal's Rule 12(b)(6) arguments depend on that labeling, it should deny that part of Amneal's motion in its entirety.

Even if the Court were to consider the labeling, however, Amneal's arguments fail for the additional reasons described below.

III. PAR PROPERLY STATES A CLAIM FOR INFRINGEMENT UNDER 35 U.S.C. § 271(e)(2)

Section 271(e)(2) of the Patent Act provides that it is an act of infringement to submit an ANDA "for a drug claimed in a patent or the use of which is claimed in a patent," if the applicant seeks approval to sell the ANDA product before the patent expires. 35 U.S.C. § 271(e)(2)(A). Here, the Patents in Suit claim the use of vasopressin to treat septic shock (the '435 Patent) and post-cardiotomy shock (the '278 Patent); [redacted]. In Counts I, III, V, and VII, Par alleges that, if approved, Amneal's commercial manufacture and sale of its Proposed Vasopressin Products would induce physicians and other medical professionals to use and administer the Products in a manner that directly infringes the Patents in Suit. Am. Compl. ¶¶ 49-57, 61, 77, 93, 109. Accordingly, Amneal's filing of its ANDAs was an act of infringement under § 271(e)(2).

Amneal argues that Par's allegations, which the Court must accept as true for purposes of Amneal's motion to dismiss, are insufficient to state a claim for infringement under § 271(e)(2) for three reasons, none of which have merit.

A. Amneal's ANDAs Seek Approval for the Same Use As Claimed By the Patents in Suit

Amneal first argues that Par does not allege that Amneal seeks approval to market its Proposed Vasopressin Products "for the uses specified in the [Patents in Suit]." Amneal Br. at 6-8. To the contrary, however, as just noted, [redacted].

Amneal asserts that the circumstances presented here "mimic" those in *Warner-Lambert*, which "compel[s] dismissal." *Id*. (citing *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1351 (Fed. Cir. 2003)). Not so. In *Warner-Lambert*, the patent at issue claimed the use of gabapentin to treat neurodegenerative diseases (such as Alzheimer's and Parkinson's diseases). Apotex filed an ANDA seeking approval to market gabapentin for an entirely different use—the treatment of partial seizures in adults with epilepsy, and "d[id] not include any indication for use in the treatment of either neurodegenerative or neurogenerative diseases." *Id*. at 1352.

The Federal Circuit noted that the FDA "grants approval to make, use, and sell a drug for a specific purpose," and that in adopting the Hatch-Waxman Act,

Congress recognized that while a single drug could be approved for more than one indication, an "ANDA applicant could seek approval for less than all of those indications." *Id*. at 1356, 1360-61. The Federal Circuit held that "Congress clearly intended to limit actions for infringement of method-of-use patents under § 271(e)(2)(A) to 'controlling use patents,' or patents that claim an approved use of a drug." *Id.* at 1362. The term "controlling use patents" refers to "patents that claim 'an indication for the drug for which the applicant is seeking approval.'" *Id.* at 1361. Warner-Lambert therefore did not have a cause of action under § 271(e)(2) because the patent at issue did not claim the indication for gabapentin for which Apotex was seeking approval (treatment of epilepsy).

[redacted]

Amneal's reliance on *AstraZeneca* is similarly flawed. There, as in *Warner-Lambert*, the patents at issue claimed the use of a drug (rosuvastatin) to treat one set of indications, and although the FDA had approved the branded product (CRESTOR®) for use in treating those indications, Apotex sought approval of its generic product only for treatment of a different indication. *AstraZeneca Pharma. LP v. Apotex Corp.*, 669 F.3d 1370, 1373-74 (Fed. Cir. 2012). AstraZeneca alleged that the Apotex's ANDA filing infringed the relevant patents, "even though

[Apotex] had not requested approval for any patented indications and had filed Section viii statements to that effect." *Id.* at 1375. The Federal Circuit again relied on Congress's recognition that a single drug could have more than one indication, noting that the Hatch-Waxman Act "allows generic manufacturers to limit the scope of regulatory approval they seek … by excluding patented indications from their ANDAs." *Id*. at 1379. Accordingly, because Apotex had submitted ANDAs seeking approval to market the drug for indications not claimed in the patents in suit, as in *Warner-Lambert*, there was no infringement under § 271(e)(2). *Id*. at 1380.

The case that is actually on point is *Bayer Healthcare LLC v. Norbrook Labs., Ltd.*, No. 08-C-0953, 2009 WL 6337911 (E.D. Wisc. Sept. 24, 2009). There, Norbrook filed an Abbreviated New Animal Drug Application ("ANADA") seeking approval for a generic version of an injectable, animal drug product used to treat bovine respiratory disease. *Id*. at *4. Bayer filed suit under § 271(e)(2), claiming that if approved, Norbrook's sale of its ANADA product would induce veterinarians to infringe its patents, which claimed the use of the drug to treat the same indication.[6] *Id*. at *4-5. Norbrook argued that Bayer failed to state a valid

[6] Although *Bayer Healthcare* involved animal drugs, rather than human drugs, and hence involved the filing of an ANADA under the Generic Animal Drug and Patent Term Restoration Act, rather than the filing of an ANDA under the Hatch-Waxman Act, "the statutory framework of the two acts is extremely similar." *Id*. at *2 n.5. Most pertinently here, just as § 271(e)(2)(A) provides that it is an act of

§ 271(e)(2) infringement claim because it sought approval for a dosing regimen (multiple-day low-doses of the drug) that was different than the dosing regimen claimed in the patents (a single high dose), and therefore was not seeking approval for a "use" claimed in a patent, as § 271(e)(2) requires. *Id*. at *9. The court rejected that argument and denied Norbrook's motion for judgment on the pleadings, reasoning that "Bayer's ′506 patent covers enrofloxacin for treating bovine respiratory disease, and Norbrook's ANADA seeks approval to use enrofloxacin to treat bovine respiratory disease," such that "Norbrook does not seek to use the drug, enrofloxacin, to treat any other condition; it seeks to use the same drug to treat the same condition." *Id*. at *10.

Like Amneal, Bayer argued that *Warner-Lambert* compelled dismissal. The court disagreed, explaining that "Norbrook improperly analogizes the distinction made in *Warner-Lambert* for the same drug treating different diseases—neuro degenerative diseases and epilepsy—to the same drug treating the same disease at different dosages, as proposed by Norbrook." *Id.* at 11. Accordingly, it held that "[a]t this juncture of the proceedings, Norbrook has not demonstrated that, as a

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infringement to submit an ANDA seeking approval "for a drug claimed in a patent ***or the use of which is claimed in a patent***," so too § 271(e)(2)(B) likewise provides that it is an act of infringement to submit an ANDA seeking approval "for a drug claimed in a patent ***or the use of which is claimed in a patent***." 35 U.S.C. § 271(e)(2)(A), (B) (emphases added). For that reason, the court in *Bayer Healthcare* based its decision on Hatch-Waxman Act case law. *Id.*

matter of law, Bayer cannot establish an infringing 'use' under § 271(e)(2)." *Id.*

Here, Amneal makes the same argument that *Bayer Health* rejected—*i.e.*, that [redacted], there is no § 271(e)(2) infringement because [redacted] The Court should reject that argument for the reasons expressed in *Bayer Health*.

B. Par's Claims are Ripe

Amneal next argues that Counts I, III, V, and VII are not ripe because they depend upon FDA's approval of a future amendment to the label for Amneal's Proposed Vasopressin Product. Amneal Br. at 8-9. However, the factual premise for that argument is simply not true: Par alleges that Amneal will induce infringement of the Patents and Suit independent of any label changes that the FDA may or may not require of Amneal.

Although Par does allege that the FDA will require Amneal to amend its labels to include explicit instructions regarding the administration of its Proposed Vasopressin Products to AA and AT genotyped patients, Par further alleges that Amneal will "induce infringement of the Patents in Suit in ways beyond just the instructions on the label." Am. Compl. at ¶ 52. And Par provides specific, detailed allegations as to how and why that is so. Par alleges, for instance, that

Amneal's sales force will affirmatively market and sell its Proposed Vasopressin Products as a generic equivalent to VASOSTRICT® which should be used and administered in the same manner as VASOSTRICT®, and that Amneal will do so with the knowledge and expectation that physicians will treat patients based on the most up-to-date clinical information available—including Par's discovery that AA and AT genotyped patients can and should be treated in accordance with the new dosage regimens claimed in the Patents in Suit, which could be a matter of life or death for those patients. *Id*. at ¶¶ 49-50, 52-53. Par further alleges that, acting in accordance with the best interests of patients, Amneal will market and sell its Proposed Vasopressin Products (if approved) with the specific intent that the Products be used to treat AA or AT genotyped patients in accordance with those patented dosage regimens. *Id.* at ¶ 54.

These allegations, which Amneal makes no attempt to rebut and must be accepted as true for purposes of Amneal's motion to dismiss, are not dependent on any amendments to the proposed labeling for Amneal's Proposed Vasopressin Products and readily state a claim under § 271(e)(2) for infringement of the Patents in Suit. *See, e.g., AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042 (Fed. Cir. 2010) ("liability for active inducement may be found 'where evidence goes beyond a product's characteristics or the knowledge that it may be put to infringing uses, and shows statements or actions directed to promoting infringement'" (citing *Ricoh Co.*

v. Quanta Computer Inc., 550 F.3d 1325, 1341 (Fed.Cir.2008)); *Mentor H/S, Inc. v. Medical Device Alliance, Inc.*, 244 F.3d 1365 (Fed. Cir. 2001) (reversing entry of JMOL of non-infringement, where substantial evidence "supports the jury's verdict that Misonix induced infringement because it sold the device with the intention that doctors would use it to perform the patented method").[7]

Indeed, this is the sort of dispute that Congress designed the Hatch-Waxman Act to resolve. As courts have recognized, the purpose of § 271(e)(2) is "to enable a court to promptly resolve any dispute concerning infringement and validity" of any patents relating to an ANDA filing. *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997). *See also Eli Lily & Co. v. Medtronic, Inc.*, 496 U.S. 661, (1990) ("Quite obviously, the purpose of subsections (e)(2) and (e)(4) is to enable the judicial adjudication upon which the ANDA and paper NDA schemes depend"). The time to resolve the dispute between the parties regarding the

[7] Par acknowledges that the Federal Circuit has held that "mere knowledge of possible infringement by other does not amount to inducement." *See Warner-Lambert*, 316 F.3d at 1364 (granting summary judgment "[i]n the absence of any evidence that Apotex has or will promote or encourage doctors to infringement the neurodegenerative method patent"). Here, however, Par's allegations go well beyond the assertion that Amneal knows of possible infringement of Par's patents. Par asserts, with good reason, that Amneal will actively encourage such infringement with the specific intent that physicians treat AA or AT genotyped patients as claimed in the Patents in Suit. Am. Compl. at ¶¶ 49-50, 52-53. Again, Amneal does not dispute those allegations or otherwise assert that they are implausible under *Iqbal* or *Twombly*.

infringement of the Patents in Suit is now, not once Amneal has obtained approval and has launched its products into the marketplace and inflicted irreparable harm upon Par.

The cases on which Amneal relies are inapposite. *AstraZeneca Pharma* is distinguishable for the reasons discussed above, while *Par Pharmaceutical, Inc. v. Luitpold Pharma., Inc.*, No. 16-cv-02290, 2017 WL 452003 (D.N.J. Feb. 2, 2017), is inapposite because that was case in which the plaintiff's claims were dependent on an allegation that the FDA would require the defendant "to adjust its product formulation in a way that will infringe the Patents-in-Suit." *Id*. at *6. That is not the case here.[8]

C. Par Properly Alleges that Amneal Will Induce Infringement of the Patents in Suit

Lastly, Amneal argues that Counts I, III, V, and VII fail to state a valid claim under § 271(e)(2) for induced infringement of the Patents in Suit, citing

[8] Amneal's reliance on *Texas v. United States*, 523 U.S. 296 (1998), is also unavailing. There, the State of Texas sought a ruling that sanctions it potentially might choose to impose at some indeterminate time in the future against some unknown under-performing school district would not violate the federal Voting Rights Act. *Id*. at 297-99. Texas had "not pointed to any particular school district" to which the sanction "is currently foreseen or even likely" to apply, and it "hope[d] there will be no need" to ever apply the sanction. *Id*. at 300. Accordingly, because the Court had "no idea whether or when" the sanction might be ordered, "the issue [was] not fit for adjudication." *Id*. Those circumstances bear no resemblance to the one presented here—where there is a defined and concrete dispute involving known parties and known circumstances regarding a particular ANDA and specified patent claims.

AstraZeneca Pharma for the proposition that "Par cannot make a claim for induced infringement under 35 U.S.C. § 271(e)(2) based on speculative off-label use." Amneal Br. at 10. However, *AstraZeneca Pharma* does not stand for that proposition. The deficiency in AstraZeneca's § 271(e)(2) claim was not that any alleged "off-label use" was speculative; rather, as discussed above, it was that Apotex's then-current ANDA did not seek approval for the "use" claimed in the patents in suit (it sought approval for the use of its gabapentin product to treat epilepsy, while the patents claimed the use of gabapentin to treat Alzheimer's and other neurodegenerative diseases). 669 F.3d at 1376-1380. In the portion of the decision Amneal cites, the Federal Circuit held that this deficiency was not remedied by AstraZeneca's allegation that the FDA would require Apotex to amend its ANDA to include approval for the claimed use. *Id.* at 1380-81. In particular, the Court found that "AstraZeneca's claims based on presumed future labeling amendments are unripe." *Id.* at 1381. Again, for the reasons discussed above, these rulings have no bearing on Par's § 271(e)(2) claims.

Amneal's reliance on *Allergan, Inc. v. Alcon Laboratories, Inc.*, 324 F.3d 1322, 1334 (Fed. Cir. 2003), *see* Amneal Br. at 11-12, is similarly misplaced. As in *Warner-Lambert* and *AstraZeneca Pharma*, the ANDA at issue sought approval for an indicated use of the drug (use of brimonidine to reduce intraocular pressure) which was different from the use claimed in the patents at issue (optic nerve and

neural protection). *Id.*, 324 F.3d at 1324. Thus, it is inapposite for the same reasons that *Warner-Lambert* and *AstraZeneca* are.

IV. PAR'S DECLARATORY JUDGMENT CLAIMS ARE PROPERLY BEFORE THIS COURT AND STATE A CLAIM UPON WHICH RELIEF CAN BE GRANTED

Amneal seeks to dismiss Par's declaratory judgment claims (Counts II, IV, VI, and VIII), both under Rule 12(b)(1) on the grounds that this Court allegedly lacks subject matter jurisdiction over those claims, and under Rule 12(b)(6) that Par allegedly fails to state a claim upon which relief can be granted. Neither ground has merit.

A. Par Alleges the Existence of an Immediate and Real Controversy Regarding Amneal's Inducement of Infringement of the Patents in Suit

In Counts II, IV, VI, and VIII, Par alleges that Amneal, if left unchecked, will knowingly and actively induce physicians and other medical professionals to treat AA and AT genotyped patients for vasodilatory shock using its Proposed Vasopressin Products (if approved) in accordance the innovative treatment regimens taught and claimed in the Patens in Suit, and seeks declaratory judgments that such conduct would constitute infringement of those Patents under 35 U.S.C. § 271(b). Amneal argues that these Counts lack the requisite "immediacy" and "reality" necessary to sustain the Court's jurisdiction over them because it is not

currently inducing infringement of the Patents. Amneal Br. at 10-12. Amneal is wrong.

MedImmune held that declaratory judgment jurisdiction requires a controversy of "sufficient immediacy and reality to warrant the issuance of a declaratory judgment," *MedImmune*, 549 U.S. at 127, but "[t]he immediacy requirement is not concerned in the abstract with the amount of time that will occur between the filing of the declaratory judgment action and the liability-creating event. An event that is several years in the future may be an appropriate subject for a declaratory judgment." *Sandoz Inc. v. Amgen Inc.*, 773 F.3d 1274, 1277 (Fed. Cir. 2014). Par need only show that Amneal has engaged in "meaningful preparation for making or using [its] product," which it indisputably has by filing its ANDAs. Amneal "need not have engaged in the actual manufacture or sale of a potentially infringing product" for declaratory judgment jurisdiction to lie. *See, e.g.*, *Cat Tech*, 528 F.3d at 881-82 (affirming the presence of declaratory judgment jurisdiction where "TubeMaster ha[d] taken significant, concrete steps" to conduct the infringing activity, and was "prepared to produce [the infringing product] as soon as it receives an order…").

This Court's opinion in *Wyeth & Cordis Corporation v. Abbott Labs*, C.A. No. 08-0230 (JAP), 2008 WL 2036805 (D.N.J. May 8, 2008), is instructive. There, Wyeth asserted claims for declaratory judgment of patent infringement

based on allegations that the defendants "intend[] to market and sell [the infringing product] immediately upon approval from the FDA…" *Id*. at *4. Although the FDA had not yet approved the defendants' application, the Court nevertheless found that declaratory judgment jurisdiction was proper. *Id.* As the court explained, "Defendants' marketing and launch of [the product] post-FDA approval is a certainty. Defendants have made their intent clear. Both [defendants] plan to sell their product at the earliest opportunity once they receive FDA approval." *Id*. at *5.

The same is true here. Par alleges that "if Amneal were to obtain FDA approval to market and sell its Proposed ANDA Products, it would market and sell [them] to hospitals and/or group purchasing organizations ("GPOs") and other distributors throughout the United States…as a generic substitute for VASOSTRICT® to be used and administered in the same manner as VASOSTRICT®." Am. Compl. ¶ 49. Amneal does not dispute that this is its intent. And as detailed above, Par alleges—without rebuttal by Amneal for purposes of its motion—that upon launch, Amneal will market and sell those Products in a manner that knowingly and actively encourages infringement of the Patents in Suit.

These allegations give rise to a real concern that, if the FDA approves Amneal's generic vasopressin product, Amneal will immediately begin to induce

infringing the Patents in Suit, a circumstance which the Hatch-Waxman Act was designed to prevent and which courts have recognized will cause significant irreparable harm to Par. *See* 35 U.S.C. § 271(e)(4)(B) (entitling a patentee to injunctive relief, as a matter of law, to prevent the launch of an infringing generic product); *Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1362 (Fed. Cir. 2008) (citing cases and noting that the at-risk launch of a generic product causes irreparable harm when it causes "price erosion and loss of market position" and the "loss of revenue, goodwill, and research and development support"); *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1063 (Fed. Cir. 2010) (affirming finding that the distribution of a generic drug and subsequent forced removal "would cause unquantifiable harm to [the patentee's] goodwill").

Amneal alleges that Par's claims "depend on multiple layers of speculation," referring to its earlier assertions that Par's claims depend on the FDA approving amendments to the labels for VASOSTRICT® and its own Proposed Vasopressin Product. Amneal Br. at 11. But as detailed above, that is not true—as with Par's § 271(e)(2) claims, Par's declaratory judgment claims do not require that either of those events occurs. Par alleges that Amneal will induce infringement of the Patents in Suit in ways beyond just the instructions on its proposed label (either the current label or any future amended label).

Amneal also alleges that these claims rest on "fluid and indeterminate" circumstances that "fail to meet constitutionally-mandated reality requirements." Amneal Br. at 11 (quoting *Matthews Int'l Corp. v. Biosafe Eng'g, LLC*, 695 F.3d 1322, 1330 (Fed. Cir. 2012)). But in *Matthews*, the alleged infringer had "never provided information regarding the specific parameters under which its units will likely be operated," rendering it "impossible to determine whether such operation could meet the claim limitations" of the patents in suit. *Id.* at 1330-31. In contrast, here Amneal has filed two ANDAs with the FDA regarding its Proposed Vasopressin Products, and Par makes substantial allegations that, upon approval, Amneal will market and sell its products in such a way as to induce infringement of the patents in suit. Unlike *Matthews*, this is a case in which "the technology in question is substantially fixed as opposed to fluid and indeterminate"; Amneal has filed its ANDAs seeking to sell vasopressin products for use [redacted], and upon approval it will do so in a way that infringes. *Cat Tech*, 528 F.3d at 882-83 (finding declaratory judgment jurisdiction where "TubeMaster does not expect to make substantial modifications to its loading device designs once production begins…once the cloud of liability for infringement is eliminated, the accused products can be produced without significant design change").

Amneal has taken specific, concrete steps towards infringing the Patents-in-Suit, and Par has every reason to believe that, as in *Wyeth*, it will launch its Proposed Vasopressin Products upon FDA approval. There is a real, immediate, and concrete controversy between the parties as to whether in doing so, Amneal will induce infringement of the Patents in Suit. This Court has subject matter jurisdiction to resolve that important dispute.

B. Counts II, IV, VI, and VIII State Valid Declaratory Judgment Claims

Amneal's final argument is that "[e]ven if the Court has jurisdiction, it should dismiss Par's § 271(b) claims." Amneal Br. at 12. That is a misnomer. Par does not assert "§ 271(b) claims." It asserts four declaratory judgment claims, seeking a declaration that if left unchecked, upon approval of its ANDAs, Amneal will knowingly and actively induce others to infringe the Patents in Suit, and hence be liable of patent infringement under § 271(b). In any event, Amneal's argument has no merit.

"In deciding a motion to dismiss, all well-pleaded allegations of the complaint must be taken as true and interpreted in the light most favorable to the plaintiffs, and all inferences must be drawn in favor of them." *St. Luke's Health Network, Inc. v. Lancaster Gen. Hosp.*, 967 F.3d 295, 299 (3d Cir. 2020) (quoting *McTernan v. City of York*, 577 F.3d 521, 526 (3d Cir. 2009)). Par need not "prove its case at the pleading stage"; rather, it "is only required to plead enough facts to

enable a court 'to draw the reasonable inference that the defendant is liable for the misconduct alleged.'" *In re Bill of Lading Transmission & Processing Sys. Patent Litig.*, 681 F.3d 1323, 1339, 1342 (quoting *Iqbal*, 556 U.S. at 678). Counts II, IV, VI, and VIII easily satisfy that standard.

Amneal asserts that "Par's [Amended] Complaint does not identify any explicit direction or instruction by [Amneal] that would lead to active infringement under § 271(b)." Amneal Br. at 13 (internal quotations omitted). But as Par has explained, that is not true.

The Amended Complaint does not contain mere conclusory allegations that Amneal will induce infringement. Rather, as described in detail above, the Amended Complaint walks through Amneal's knowledge of, and specific intent to induce infringement of, the Patents in Suit, as well as how and why this inducement will occur. And, Par alleges more than just that Amneal has knowledge that physicians and other will use its Proposed Vasopressin Products in an infringing manner, specifying affirmative steps that Amneal will take to actively encourage such infringement. These allegations are similar to, and even stronger than, allegations that courts have found sufficient to sustain induced infringement claims. *See Lifetime Indus., Inc. v. Trim-Lok, Inc.*, 869 F.3d 1372, 1380 (Fed. Cir. 2017) (reversing dismissal of induced infringement claim where "Lifetime pleaded that Trim-Lok had knowledge of the [patent], it's scope, and the products covered

thereby" and then "assisted in or directed the installation of exactly the same type of seal as the one described in the patent"); *Telecomm Innovations, LLC v. Ricoh Co.*, 966 F. Supp. 2d 390, 395 (D. Del. 2013) (finding allegations of inducement sufficient where the complaint specified that the defendants provided technical support and instruction "knowing such acts would cause infringement"); *WAG Acquisition, LLC v. Multi-Media, LLC*, No. 14-2340 (ES)(JAD), 2015 WL 5310203, at * (D.N.J. Sept. 10, 2015) (denying motion to dismiss inducement claims where "WAG alleges that Defendants know that users employ the infringing [product], and that they *intend* this consequence or are willfully blind to it").

Amneal tries to dismiss these allegations as mere "speculation." Amneal Br. at 13. However, at the pleadings stage, which is where we are, the Court must "assume all remaining factual allegations to be true, construe those truths in the light most favorable to the plaintiff, and then draw all reasonable inferences from them." *Connelly*, 809 F.3d at 790. "Nothing in *Twombly* or its progeny allows a court to choose among competing inferences as long as there are sufficient facts alleged to render the non-movant's asserted inferences plausible." *In re Bill of Lading*, 681 F.3d at 1340. Par has alleged sufficient facts in support of its claims to draw the reasonable inference that upon approval of its ANDA, Amneal will

take steps to knowingly and actively induce infringement of the Patents in Suit. Par therefore has adequately stated a claim upon which relief can be granted.

V. CONCLUSION

For the foregoing reasons, the Court should deny Amneal's motion to dismiss.

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Respectfully submitted,

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